**IN THE UNITED STATES DISTRICT COURT**
**FOR THE EASTERN DISTRICT OF NEW YORK**

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| SHAFIGHEH KOUBLANI,<br><br>Plaintiff,<br><br>-vs-<br><br>COCHLEAR LIMITED AND COCHLEAR AMERICAS,<br><br>Defendants. | : | 2:20-cv-01741-DRH-AYS<br><br>**Oral Argument Requested** |

**DEFENDANT COCHLEAR AMERICAS CORPORATION'S**
**REPLY MEMORANDUM IN FURTHER SUPPORT OF ITS MOTION TO DISMISS**


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Plaintiff's Opposition[1] is based entirely on two fictions – her erroneous contention that the MRI Kit is a Class II device and thus is not subject to federal requirements via the FDA's approval of the CI522 Device's PMA Supplement, and her equally inaccurate assertion that she can adequately plead a product liability claim without putting forth a single allegation of fact to plausibly suggest that the MRI Kit was defective. Her claims should be dismissed.

## I. THE MRI KIT IS A CLASS III DEVICE AND PLAINTIFF'S CLAIMS ARE PREEMPTED

Plaintiff concedes, as she must, that state-law product liability claims are preempted when they involve a Class III device approved pursuant to the FDA's rigorous PMA process, unless the complaint alleges violation of a specific federal requirement applicable to the device (which Plaintiff has not done here). She also concedes that the CI522 Device is a Class III device, and acknowledges that in July 2016 the FDA approved a PMA Supplement to expand the CI522 Device's indication to allow it to remain implanted during certain MRI procedures provided that CAM's MRI Kit is used. Nevertheless, in an effort to escape preemption, she contends that the FDA's approval of the PMA Supplement "do[es] not extend to the MRI Kit and shield it from State law claims," because, according to Plaintiff, the CI522 Device and the MRI Kit are "separate products" and the MRI Kit purportedly is separately categorized as a Class II device under FDA regulations. (Opp. at 1-2). Plaintiff is wrong on all counts.

### A. The MRI Kit Was Approved by the FDA Pursuant to Its Approval of the CI522 Device's PMA Supplement

As the FDA's approval order makes clear, the MRI Kit was approved by the FDA as part of the CI522 Device's 2016 PMA Supplement. (*See* Mot., Ex. A). Plaintiff misleadingly copies

[1] CAM refers herein to Plaintiff's Opposition to CAM's Motion to Dismiss the Amended Complaint ("Opposition" or "Opp.") and CAM's Memorandum in Support of Its Motion to Dismiss ("Motion" or "Mot."). Capitalized terms have the meanings set forth in CAM's Motion.

and pastes a portion of the FDA database listing for the PMA Supplement approval into its brief, and argues that because the MRI Kit is not specifically listed in the "Device" field, the FDA did not approve and impose federal requirements on the MRI Kit.[2] But Plaintiff tellingly omits the actual Approval Order Statement from the database entry, which states that the Device's newly approved indication is dependent on the use of CAM's MRI Kit:

> **Approval Order Statement.**
>
> Approval requested for 1) a change in indications to allow MRI of implant recipients at 1.5T with the implant magnet in place for CI512, CI522, CI532, CI422, CI24REH, CI24RE(CA), and CI24RE(ST) ***provided that a Cochlear-supplied MRI kit is used*** . . . .

(Mot., Ex. A (emphasis added)). It simply is not plausible that the FDA would approve a change in indication to allow an implantable medical device with magnetic components to remain in place during MRI procedures only where a specific accessory provided by the device manufacturer is used, without approving and imposing requirements on that accessory.[3]

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[2] Tellingly, Exhibit C to Plaintiff's Opposition, which she concedes reflects PMA approval for an accessory to a Class III device, also does not list the accessory in the "Device" field. (Opp., Ex. C). Nor is the "Device" field for the 2016 approval of the PMA Supplement that included the MRI Kit at issue here limited to the implant itself as Plaintiff contends (Opp. at 10). Rather, it lists the "Nucleus Cochlear Implant System," ***not*** just the CI522 Device as did the listing for the 2015 approval of the Device's original PMA supplement. (Compare Mot., Ex. A *with* Ex. B). If anything, the 2016 entry supports the position that the FDA views the MRI Kit as part of the "Nucleus Cochlear Implant System," and not as a separate device as Plaintiff argues.

[3] Plaintiff's Opposition is replete with inaccuracies regarding the contents of the PMA Supplement and what it does or does not contain with respect to the MRI Kit. For example, Plaintiff erroneously states that the "Supplemental PMA application only involved the Implant and not the Kit," (Opp. at 11), and that CAM "merely mentioned the MRI Kit in the Supplemental PMA it filed for the Implant." (Opp. at 13, *see also id.* at 3, 9, 15). CAM is confident that neither Plaintiff nor her counsel has ever seen the PMA Supplement, a confidential submission that is not publicly available and does not comport with Plaintiff's assertions, which begs the question as to how they can make representations to the Court regarding its contents consistent with their obligations under FRCP 11(b)(3). While CAM recognizes that the Court is constrained by the allegations in the pleadings and public records subject to judicial notice, and contends that those sources are sufficient to confirm that the MRI Kit is a Class III device subject to federal requirements, Plaintiff's unsupported and implausible speculation regarding the contents of the PMA Supplement is completely inaccurate.

Indeed, the MRI Kit is ***not*** a "separate product" from the CI522 Device as Plaintiff contends. Its sole purpose is to hold the CI522 Device's implanted magnet in place during an MRI procedure to allow the CI522 Device to function in accordance with its indicated use. (*See* Compl. ¶ 22 (acknowledging that the MRI Kit was "specifically designed and sold by Defendants to protect [Cochlear] implant recipients . . . from the dangers associated with undergoing an MRI procedure with the Magnet in place")). As noted in CAM's opening brief, the MDA expressly defines a device to include "any component, part or accessory," 21 U.S.C. § 321(h), and for this reason courts throughout the country have found both "components" and "accessories" of Class III devices to constitute Class III devices for purposes of preemption. (*See* Mot. at 19 & n.17).[4] Plaintiff contends, based on FDA guidance published a year after the FDA's 2016 approval of the PMA Supplement, that an "accessory" must "support, supplement and/or augment the performance of one or more parent devices." (Opp. at 12 & Ex. B at 5). The MRI Kit clearly meets this definition – without the MRI Kit, the CI522 Device cannot perform its FDA-approved function of remaining *in situ* during certain MRI procedures. As an accessory of the PMA-approved CI522 Device, the MRI Kit "falls within the scope of the device-related PMA approval that [Defendants] received." *Kubicki v. Medtronic, Inc.*, 293 F. Supp. 3d 129, 175 (D.D.C. 2018).[5] None of the arguments advanced by Plaintiff changes the fact that the FDA approved the MRI Kit through the PMA process and preemption therefore applies.

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[4] CAM does not argue that the MRI Kit is a "component" of CI522 Device. However, the same rationale that several courts have relied upon in holding that "components" of Class III devices are themselves Class III devices for purposes of preemption applies equally to "accessories." (*See* Mot. at 19 (citing cases)).

[5] The 2017 Guidance cited by Plaintiff also makes clear that, at the time the MRI Kit was approved, the FDA determined classification of device accessories "by inclusion in the same classification as the parent device," unless the FDA had created a "unique, separate classification regulation for the accessory," which "traditionally [was] considered for accessory types that may be used with multiple parent devices or that have unique standalone functions." (Opp., Ex. B at

### B. The MRI Kit Is Not an "MRI Convenience Kit" and Has Not Been Classified as a Class II Device

Plaintiff also argues that the FDA specifically identified the MRI Kit as a Class II device that is exempt from 510(k) clearance requirements. Not so. Plaintiff points to non-binding FDA guidance from 1997 entitled "Convenience Kits Interim Regulatory Guidance," which exempted certain types of generic convenience kits, including "MRI Disposable Kits." (Opp. at 6, 9 & Ex. A at 14). But even a cursory review of the document shows that the MRI Kit at issue here is ***not*** a "convenience kit." The exemption only applies to "generic types of kits" "comprised of ***legally marketed devices*** that are simply being assembled in kit form strictly for the 'convenience' of the purchaser or user" and "that do[ ] not modify the intended use(s) of the individual kit components." (Opp., Ex. A at 3-4).[6] Components of convenience kits must be "purchased in finished form, i.e., they should be packaged, labeled, etc., consistent with their legal marketing authorization." (*Id.*). CAM is not an "assembler of convenience kits," and the MRI Kit is not a generic kit comprised of other marketed devices in finished form assembled for the convenience of the user – it is a unique product designed and marketed for the sole purpose of stabilizing implant magnets for patients implanted with Defendants' cochlear implants. (Compl. ¶ 22).

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2-3). The MRI Kit is not subject to a separate classification regulation, does not have unique standalone functions and is not designed or intended to be used with any parent devices other than Defendants' implants.

[6] As explained in CAM's opening brief, the FDA enacted a regulation in 2017, the year after the approval of the MRI Kit via the PMA Supplement, that was based on the 1997 guidance. Like the 1997 guidance, however, that regulation makes clear that the exemption only applies to "a generic type of Class I or II device . . . only to the extent that the device has existing or reasonably foreseeable characteristics of commercially distributed devices within that generic type," and where it is not "intended for a use different from the intended use of a legally marketed device in that generic type." (Mot. at 17-18 (citing 21 C.F.R. §§ 892.9, 892.1000)). It also explains that a manufacturer submitting a premarket notification under the exemption "cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part but shall state why the device is substantially equivalent to other devices." (*Id.* at 18 n.16 (quoting 21 C.F.R. § 892.1(b)).

Indeed, the FDA specifically approved the change in indication "provided that ***a Cochlear-supplied*** MRI kit is used." (Mot., Ex. A). By definition, such a kit is not "generic." And, if the MRI Kit was a generic Class II "convenience kit" as Plaintiff contends, the FDA would have required CAM to list the Kit under its establishment registration. (*See* Opp., Ex. A at 4 (noting that assemblers of convenience kits are still required to comply with registration and listing requirements)). It did not. Instead, it was approved through the PMA process.

## II. PLAINTIFF'S CLAIMS ARE INADEQUATELY PLED

CAM cited numerous cases in which boilerplate product liability claims that merely parrot the elements of various causes of action, without identifying any defect or missing warning, have been dismissed for failure to meet applicable pleading standards. (Mot. at 21-25). Plaintiff tellingly does not address a single one of those cases, which are directly on point and rejected conclusory allegations similar (and in some cases almost identical) to Plaintiff's here.

The problem with Plaintiff's Complaint – and the reason it must be dismissed – is that it fails to explain how or even whether her PMA-approved MRI Kit was defective. Plaintiff does not allege any facts suggesting a manufacturing or design defect, or a failure to warn against some specific circumstance or condition that would have caused her healthcare providers to reconsider using the MRI Kit. She merely states that the MRI Kit did not prevent her magnet from becoming dislodged, and then formulaically recites the elements of various causes of action. Under *Twombly* and *Iqbal*, that will not do.

Indeed, Plaintiff's Opposition aptly demonstrates the insufficiencies of her Complaint. Plaintiff spends several pages quoting cases that set forth the elements of the various causes of action asserted, and then quoting conclusory allegations from the Complaint that repeat these various elements. (Opp. at 20 (listing elements of negligence claim and tying those elements to conclusory statements in the Complaint), 22 (strict liability claim), 23-24 (failure-to-warn claim),

24-25 (implied warranty claim), 25-26 (express warranty claim). She fails, however, to cite to any ***facts*** to support these conclusory statements – because the Complaint contains none. At bottom, the only fact she alleges is that the MRI Kit did not function as intended. But the mere allegation that a device did not perform as intended is not by itself indicative of a defect. *See, e.g.*, *Bertini v. Smith & Nephew, Inc.*, No. 13 CIV. 0079 BMC, 2013 WL 6332684, at *3 (E.D.N.Y. July 15, 2013).

Plaintiff cites few cases that actually address the ***pleading*** requirements for her claims, and those cases are easily distinguished. *Williamson v. Stryker Corp.* (Opp. at 22, 26), for example, involved claims against the manufacturer of surgically implanted knee devices that broke after implantation. No. 12 CIV. 7083 CM, 2013 WL 3833081, at *1 (S.D.N.Y. July 23, 2013). The court declined to dismiss manufacturing defect claims notwithstanding the plaintiff's failure to allege specifics regarding manufacturing process, but she had alleged ***facts*** to show an actual defect that plausibly could have been caused by a manufacturing deviation. *Id.* at *5. Specifically, she alleged that x-rays had "revealed a total mechanical failure" of one implant and that the other "was overstressed and that the screws in the implant were bending, broken and/or otherwise malfunctioning." *Id.* at *5 (quoting complaint). No such allegations are present here. Similarly, in declining to dismiss the plaintiff's express warranty claim, the *Williamson* court noted that she had specifically identified the representations she relied upon in deciding to undergo implantation, including specific conversations with defendant's employees who falsely represented that the device had never broken before. *Id.* at *9-10. Again, the detailed allegations that survived dismissal in *Williamson* are a far cry from Plaintiff's vague allegations here.

*Coene v. 3M Co.* (Opp. at 19) involved a plaintiff who developed silicosis after breathing in silica dust from powder coatings manufactured by the defendants, but could not identify the

name of the specific product he ingested. No. 10-CV-6546 CJS, 2011 WL 3555788, at *3 (W.D.N.Y. Aug. 11, 2011). The court found that was not fatal to his claim, but unlike the Complaint here, the *Coene* complaint identified the specific defect at issue in the coating – that it contained silica which when inhaled can cause silicosis. *Id.* at *1, 3.[7] *Saladino v. Stewart & Stevenson Servs., Inc.* involved a post-trial motion, not a motion to dismiss, and does not address the pleading standard for failure-to-warn claims. 704 F. Supp. 2d 237, 247 (E.D.N.Y. 2010) (tractor manufacturer failed to warn of "latent danger posed by the [tractor] hood's ability to flip back 180 degrees"). It certainly does not stand for the proposition that a plaintiff can plead a claim simply by stating that a defendant "fail[ed] to communicate the dangers and hazards associated with the foreseeable and recommended use of the MRI Kit." (Opp. at 24); *see, e.g., Surdo v. Stamina Prod., Inc.*, No. 15-CV-2532, 2015 WL 5918318, at *5 (E.D.N.Y. Oct. 9, 2015) (dismissing claim where plaintiff "does not specify the danger he was not warned about").

Plaintiff also cites a few cases for the proposition that she should be entitled to a relaxed pleading standard because the details of the design and/or manufacturing process are not publicly available. (Opp. at 20, 22-23). But again, those cases only highlight the deficiencies of her Complaint. In *Cowan v. Costco Wholesale Corp.* (Opp. at 23), the plaintiff "allege[d] that the Product's design was defective in that the defendants utilized extremely flammable and

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[7] *Winslow v. W.L. Gore & Assoc, Inc.*, which involved a claim for defective pelvic mesh found to have deteriorated after it was surgically removed, is also inapposite, because the plaintiff "specifically identified the 'nature of the alleged defect' as being deterioration of the mesh device." No. CIV.A. 10-116, 2011 WL 866184, at *2 (W.D. La. Jan. 21, 2011). Same with the other pelvic mesh case Plaintiff cites. *See Coleman v. Bos. Sci. Corp.*, No. 1:10-CV-01968, 2011 WL 1532477, at *1 (E.D. Cal. Apr. 20, 2011). In *Hemme v. Airbus, S.A.S.*, the plaintiff plausibly alleged that wiring was defective because it "was subject to wet arcing, dry arcing, chafing, hydrolysis and pyrolization" and therefore sent erroneous signals to an aircraft's flight computer and caused the plane to crash. No. 09 C 7239, 2010 WL 1416468, at *1 (N.D. Ill. Apr. 1, 2010). The Complaint here identifies no such defect – it simply states that the MRI Kit was defective.

combustible materials and hazardous components," and specifically identified no less than six purportedly safer alternative designs in the complaint. No. 15-CV-05552 (PKC), 2017 WL 59080, at *2 (E.D.N.Y. Jan. 5, 2017). The *Cowan* court expressly distinguished the complaint in that case from one of the cases CAM cited in its opening brief, in which "'the [plaintiffs] merely plead the legal conclusion that [the product] was defective' and 'do not plead facts alleging the existence of a feasible alternative design." *Id.* at *3 (quoting *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 577-78 (E.D.N.Y. 2012)).[8] As *Cowan* and *Reed* make clear, Plaintiff's Complaint here falls short. Similarly, in *Burgos v. Satiety, Inc.* (Opp. at 23), the court excused plaintiff's inability to plead exactly how a surgical device's manufacture violated the terms of its approval, but there the plaintiff had at least alleged that the device "malfunctioned," and "supported that allegation by reference to the incident report filed by the [ ] investigation team that performed her [surgical] procedure [using the device]." No. 10-CV-2680 JG RLM, 2011 WL 1327684, at *3 (E.D.N.Y. Apr. 5, 2011). Plaintiff here has not alleged that the MRI Kit "malfunctioned," or any other facts that would allow this Court to infer the existence of a manufacturing defect.

Finally, Plaintiff argues that her allegations regarding the discontinued distribution of the MRI Kit (which she inaccurately and inappropriately characterizes as a "recall," *see* Mot. at 8 n.9) "provides ample circumstantial evidence that the MRI Kit was faulty." (Opp. at 21). Yet, she cites no case law suggesting that a manufacturer's decision to discontinue a product, with

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[8] Plaintiff also cites *Ohuche v. Merck & Co.*, in which a pro se plaintiff was not required at the pleading stage to prove an alternative design for a vaccine, but the plaintiff had at least identified why she believed it was defective, and the court noted that "submissions of a pro se litigant should be held to less stringent standards than formal pleadings drafted by lawyers." No. 11 CIV. 2385 SAS, 2011 WL 2682133, at *2 (S.D.N.Y. July 7, 2011). Courts have since clarified that *Ohuche* "cannot be read to undermine the general requirement that an alternative design must be pleaded, even if it is not fully developed at the pleading stage." *Kennedy v. Covidien, LP*, No. 118CV01907LTSKNF, 2019 WL 1429979, at *3 (S.D.N.Y. Mar. 29, 2019).

nothing more, is sufficient to allege a defect. Indeed, courts have rejected that very argument. For example, one court recently dismissed claims involving a prescription eye lubricant where the complaint alleged only that defendant had voluntarily recalled the product:

> [T]his inquiry turns on one question: whether Christian can plausibly allege ActivEyes Nighttime was defective by relying only on her allegation that a voluntary recall notice was issued. It is true that Rule 8 does not "demand[ ] highly specific factual allegations to satisfy this plausibility requirement." The rule, however, demands "more than a sheer possibility that a defendant has acted unlawfully." And in products liability cases, "[i]t is not enough for Plaintiffs to simply rely on their basic injury allegations and argue that the product was somehow defective because it was 'dangerous.'" But that is what Christian has done in this case by referring to only the voluntary recall notice, and alleging no facts about the defect.
>
> Standing alone, a voluntary recall notice which fails to identify a specific contamination issue and expressly states that no product has been identified as out-of-specification does not constitute a plausible allegation of a product defect. Accordingly, the strict liability and negligence claims in Christian's proposed Second Amended Complaint cannot survive a Rule 12(b)(6) motion, and any amendment would be futile.

*Christian v. Altaire Pharmaceuticals, Inc.*, No. CV 5:20-306-DCR, 2020 WL 6051255, at *5 (E.D. Ky. Oct. 13, 2020) (citations omitted); *cf. Hughes v. Stryker Sales Corp.*, No. 08-0655, 2010 WL 1961051, at *4 (S.D. Ala. May 13, 2010), *aff'd*, 423 F. App'x 878 (11th Cir. 2011) (finding that "it would be an unreasonable and unsupportable inferential leap for a finder of fact to conclude" that a product recall, alone, gives rise "to [an] inference that the actual device implanted in [plaintiff] had a defect").

Instead, Plaintiff cites the general proposition that "a plaintiff may rely upon the circumstances of an accident to prove the existence of a manufacturing defect if the product did not perform as intended and the possibility of other causes has been excluded." *Williamson*, 2013 WL 3833081, at *5 (S.D.N.Y. July 23, 2013). Of course, Plaintiff is not relying on the "circumstances surrounding the accident" like the plaintiff in *Williamson*, who alleged that the devices at issue broke due to a "total mechanical failure" and "bending, broken or otherwise

malfunctioning screws." *Williamson*, at *5. Plaintiff here alleges no facts about the "accident" or the MRI Kit's role therein. Nor has she alleged that the possibility of other causes has been excluded – in fact, she filed a verified statement attesting that her medical providers negligently performed her MRI and failed to follow guidelines and manuals in doing so. (Mot., Ex. D, ¶ 3).

## III. PLAINTIFF SHOULD NOT BE GRANTED LEAVE TO ONCE AGAIN AMEND HER COMPLAINT

Plaintiff requests leave to amend her Complaint but provides no explanation as to what additional facts she could plead to state a viable claim. That alone is sufficient grounds to deny her request. *See, e.g.*, *Food Holdings Ltd. v. Bank of Am. Corp.*, 423 Fed. App'x 73, 76 (2d Cir. 2011) (denying plaintiffs' request to amend "on the final page of their brief in opposition to defendants' motion to dismiss, in boilerplate language and without any explanation as to why leave to amend was warranted"); *Credit Chequers Info. Servs., Inc. v. CBA, Inc.*, 205 F.3d 1322 (2d Cir. 2000) (denying request because plaintiff "ha[d] given no indication of what amendment [was] proposed that would state a valid claim for relief").

Amendment also would be futile. Plaintiff's briefing makes clear that she cannot allege the violation of any federal requirement applicable to the MRI Kit, and thus her claims cannot escape preemption. Similarly, it is clear she cannot add any non-conclusory allegations of defect. The Court already allowed Plaintiff to amend after the parties exchanged pre-motion letters. She used that opportunity to make cosmetic changes to the Complaint, but did not assert additional factual allegations to raise her conclusory claims above a speculative level. If she could not do so then, there is no reason to believe she can now. *See Kravitz as Tr. of Aegean Litig. Tr. v. Tavlarios*, No. 19 CIV. 8438 (NRB), 2020 WL 3871340, at *12 (S.D.N.Y. July 8, 2020) (denying vague request to amend when plaintiff had already been given the opportunity to amend after the exchange of pre-motion letters).

New York, New York
October 30, 2020

Respectfully submitted,

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